510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the MRII Varioguide Drill Kit.

1. Company Making the Submission:

Name of Owner:	**MRI Interventions, Inc.**
Address:	**5 Musick** **Irvine, CA 92618**
Telephone:	**949-900-6833, 949-584-8517**
Fax:	**949-900-6834**
Contact:	**Edward Waddell**
E-mail:	**ewaddell@mriinterventions.com**

2. Device Name:

Common Name:	Drill Kit
Proprietary Name:	Varioguide Drill Kit
Classification:	Class II
Regulation Number:	882.4310
Product Code:	HBE

3. Predicate Device:

MRII Cranial Drill and accessories, K122456

4. Intended Use Statement:

The VarioGuide Drill Kit used in conjunction with BrainLab's VarioGuide is intended for creating an access point in the skull during intracranial procedures. The device is not intended for implant. This device is intended for "single patient use only."

5. Description of Device:

The VarioGuide Drill Kit is a set of components that work in conjunction with the VarioGuide and each other to guide a drill bit along a desired trajectory to make an access hole in the skull. The components that comprise the VarioGuide Drill Kit are a Drill Guide, a 3.4mm Drill Bit, a Lancet, two Depth Stops and a Device Guide. The Drill Guide is made from Peek and has a 316L Stainless Steel tip which is pressed into the Drill Guide body. The Drill Guide Tip has two unique features. First, the tip has a double-chamfered edge which allows the tip to bite

into the bone and that also prevents the tip from bending over. The second feature is windows that allow drilled material to exit through the tip and thus prevents the drill bit from binding. The Drill Guide is used to constrain the drill bit during access hole creation to a predetermined trajectory. The Drill Bit is made from 316L Stainless Steel and is used to create an access hole through the skull. The Drill Bit tip is designed so that the amount of drill walk at the start of drilling is limited. This feature also helps Drill Bit to maintain its trajectory. The Lancet is made from 316L Stainless Steel and has a sharp point at the distal end to allow the Lancet to pierce the Dura and/or Pia. The Lancet has a reduced section (0.60" long) which allows the Lancet to pass through the skull without any wall interference. The Depth Stops are made from 316L Stainless Steel and are used in conjunction with the Drill Bit and Lancet to set the desired depth. The Device Guide is made from Peek and is used to guide an instrument (such as a catheter) on a predetermined path. The Device Guide is available in two sizes, 0.075" for the small and 0.085" for the large.

6. Summary of the Technological Characteristics of the Device Compared to the Predicate Device

	MRI VarioGuide Drill Kit	**Predicate Device: MRII Cranial Drill K122456**
Classification	21 CFR 882.4310	21 CFR 882.4300
Product Code	HBE	HBG
Intended Use	The VarioGuide Drill Kit used in conjunction with BrainLab's VarioGuide is intended for creating an access point in the skull during intracranial procedures. The device is not intended for implant. This device is intended for "single patient use only."	The MRII Cranial Drill is intended to provide access through the skull for ventriculostomy and other neurological procedures, such as biopsy or catheter placement, in proximity of an MR scanner of 3T maximum field strength. The MRII Cranial Drill is intended for single use only
Environment	OR	OR or MRI Suite
Drill Bit Included with Drill	No	No
Integral Bit	Yes (316L SS)	Yes (316L SS)
Drill Bit Sizes	3.4mm	2.0mm 3.2mm
Toolless Adjustable Depth Stop	Yes	Yes
Packaging	Sterile, Sealed Tray, Inside Sterile Tyvek Pouch	Sterile, Inside Double Sterile Tyvek Pouch

7. **Testing:**

   Testing to applicable standards has been completed with acceptable outcomes. Design Verification was performed with acceptable results, the tests demonstrated that the VarioGuide Drill Kit functions as intended and is substantially equivalent to the legally marketed device.

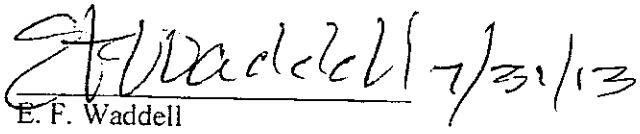
8. **Rx or OTC:**

   The Varioguide Drill Kit is an Rx prescription device per 21 CFR Part 801, Subpart D.

9. **Substantial Equivalence:**

   The VarioGuide Drill Kit is as safe and effective as the predicate MRI Cranial Drill and accessories. The VarioGuide Drill Kit has the same intended use and similar indication, technologies characteristics, and principles of operation as a predicate device. The minor technological differences between the VarioGuide Drill Kit and its predicate devices raise ne new issues of safety and effectiveness. Performance data demonstrates that the VarioGuide Drill Kit is as safe and effective as the MRI Cranial Drill and accessories. Thus, the VarioGuide Drill Kit is substantially equivalent.

MRI Interventions, Inc.



E. F. Waddell
Director of Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 20, 2014

MRI Interventions, Inc.
Mr. Edward Waddell
5 Musick
Irvine, CA, 92618

Re: K132436
Trade/Device Name: Varioguide Drill Kit
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered simple cranial drills, burrs, trephines, and their accessories.
Regulatory Class: Class II
Product Code: HBE
Dated: February 14, 2014
Received: February 18, 2014

Dear Mr. Waddell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132436

Device Name
Varioguide Drill Kit

Indications for Use *(Describe)*

The VarioGuide Drill Kit used in conjunction with BrainLab's VarioGuide is intended for creating an access point in the skull during intracranial procedures. The device is not intended for implant. This device is intended for "single patient use only."

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joyce M. Whang -S

PSC Publishing Services (301) 443-6740 EF

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